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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,196	04/20/2004	Marlene Bainbridge	BC-0234-US04	3195

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GAMBRO, INC
PATENT DEPARTMENT
10810 W COLLINS AVE
LAKEWOOD, CO 80215

EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/709,196	BAINBRIDGE ET AL.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *14 and 19-23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/22/04, 2/14/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1-24 are objected to because of the following informalities: Claim 1 recites the step of determining or selecting the blood component to be collected twice within the claimed procedure. It is unclear which step (collecting donor information or generating a list) actually determines which blood component is to be collected. For the purposes of examination, the Examiner has interpreted the claim to mean that the generation of the list determines the component to be collected. Appropriate correction is required.

2. Claim 13 recites the step of establishing an AC "ration." Examiner has interpreted the claim to mean "ratio," and that the ratio is expressed as a percent of a whole. Appropriate correction is required.

3. Claim 19 recites the limitation "multiplied by the desired fluid balance percentage resulting in the donor/patient." It is unclear what the "resulting" refers to. Examiner has interpreted the claim such that "resulting" means merely the desired fluid balance percentage in the patient. Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 5-8, 15-18, and 25-36 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,658,240 to Urdahl et al.

In the specification and figures, Urdahl discloses the device and method claimed by applicant. With regard to claim 1, Urdahl discloses a method for extracorporeal collection of a blood component from a donor that uses donor-specific characteristics to control the collection procedure (see column 1, lines 25-60). Donor-specific information, such as donor blood type, may be used to select a collection protocol, such as red blood cell collection (see column 23, lines 10-20). Various donor information is collected and entered into a central input station 148. Once the data is collected and/or edited, the central input station generates a list or display of patient data (corresponding to applicant's list generation step), including process parameters for controlling the component collection device 18, including an initial procedure order (corresponding to applicant's use of the list to select a blood component to be collected, since the procedure order determines the component to be collected; see column 23, line 51 through column 24, line 9, column 14, lines 25-37)). Once the donor-specific protocol has been entered into blood component collection device 18, the donor 14 is connected to the collection device 18, blood flows from the donor into the collection device, and the collection device separates the whole blood into its constituent portions (see column 5, line57 through column 6, line 10). The device may collect a portion of the separated blood such as plasma in a plasma collection bag 54 and return the unused portion of the blood, such as RBC/WBC to the donor (see column 6, lines 6-28).

With regard to claim 3, Urdahl discloses that after the RBC are separated from plasma in the first stage, additional plasma may be separated from a collected platelet fraction in a second stage, therefore allowing a portion of the plasma collection step to be performed after the RBC collection step, meeting the limitations of the claim (see column 7, lines 48 through column 8, line 12).

With regard to claims 5-6, Urdahl discloses that the extracorporeal blood processing and collection system 18 may be operatively connected to the central input station 148 and interface module 16, such that the entire combination may be categorized as a blood component collection control and information communication system (see column 23, lines 21-42). The input data station generates a list of patient data and collection options based on entered patient parameters. Therefore, the combined system, including the input station and the collection system 18 operates as claimed by applicant, meeting the limitations of the claims.

With regard to claims 7-8 and 15, Urdahl discloses that various patient parameters such as patient height, weight, hematocrit, and blood component precount (corresponding to applicant's platelet count), may be entered at the central input station to control the component collection procedure (see column 14, lines 8-37).

With regard to claims 16 and 17, Urdahl discloses that the initial procedure order may comprise a platelet collection procedure or a double platelet procedure (see column 14, lines 56-67, column 23, lines 10-20).

With regard to claim 18, Urdahl discloses that the device and method may comprise the simultaneous collection or more than one component type, which may be

selected from red blood cells, white blood cells, and/or plasma, thereby meeting the limitations of the claim (see column 23, lines 5-20).

With regard to claim 25, Urdahl discloses an extracorporeal blood processing machine 18 that is connected to a central input station 148 and interface module 16 that accept patient data and generate a procedure order based on the data (see column 23, line 51 through column 24, line 9, column 14, lines 25-37). The device 18 has a centrifuge rotor (not shown) that receives whole blood and separates it into plasma and red blood cells (see column 6, lines 6-67). The device may collect a portion of the separated blood such as plasma in a plasma collection bag 54 and return the unused portion of the blood, such as RBC/WBC to the donor (see column 6, lines 6-28).

With regard to claim 26, Urdahl discloses that the device 18 may be used for several different blood collection procedures (see column 23, clines 5-20), indicating that the machine may be adapted to accept tubing and bag set options related to the selected blood collection procedure. Applicant's recitation that the device is "adapted to" accept various tubing and bag systems indicates only that the prior art device should be capable of similar adaptation. Since Urdahl discloses that the device may be used for various procedures, it is capable of being "adapted to" perform as claimed by applicant.

With regard to claims 27-36, applicant recites the operation of the claimed device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, the Urdahl device discloses all the structural limitations claimed by

applicant. The central input station 148 and interface module 16 are capable of accepting the data claimed by applicant and are capable of generating the claimed reports and controlling the blood collection procedure as claimed by applicant, meeting the limitations of the claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 2, 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,658,240 to Urdahl in view of US 5,653,887 to Wahl et al.

In the specification and figures, Urdahl discloses the method substantially as claimed by applicant (see rejection above) with the exception of loading a desired tubing set or setting a desired packing factor.

With regard to claim 2, Urdahl discloses that the blood separation device 18 may be used for various separation procedures, indicating that there are a plurality of tubing and bag set options that may be used with the machine (see column 23, clines 5-20). Wahl discloses a blood separation device and method wherein the device prompts the operator to load a selected, appropriate blood processing cassette 110 on the machine in preparation for the desired separation procedure (see column 53, line 42 to column 54, line 67). Since Urdahl discloses that the machine may be used for various

procedures, and Wahl discloses the step of loading an appropriate cassette and tubing set 110 on the separation machine, the disclosures suggest that selection and loading of an appropriate tubing set on an apheresis machine is known in the art. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the step of loading an appropriate tubing set onto an apheresis machine, as taught by Wahl, to the apheresis procedure disclosed by Urdahl, since the disclosures suggest that such selection and loading is well-known in the art of blood separation and collection.

With regard to claims 9-12, Wahl discloses a blood apheresis device and method that adjusts the rotational speed of the rotor to create a predetermined desired packing factor of the separated components to maximize efficiency and prevent overcrowding (see column 37, lines 20-40). Wahl specifically discloses that the predetermined packing factor may be around 13 (see column 8, lines 28-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to set a packing factor as disclosed by Wahl in the separation method disclosed by Urdahl in order to maximize apheresis efficiency without damaging the collected cells, as taught by Wahl (see column 37, lines 20-40).

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,658,240 to Urdahl in view of US 5,695,653 to Gsell.

In the specification and figures, Urdahl discloses the method substantially as claimed by applicant (see rejection above) with the exception of collecting some RBCs after the plasma collection step.

Gsell discloses a device and method for apheresis in which plasma-rich fluid is separated and collected in satellite bag 40 while plasma-poor fluid (such as RBCs) are repeatedly recirculated through the separation device until satellite bag 20, 30, contains a predetermined concentration of the desired component (see column 20, lines 21-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to alter the method disclosed by Urdahl to include a recirculation and later collection of RBCs as disclosed by Gsell in order to obtain a desired amount or concentration of RBCs in the collection bags, as taught by Gsell (see column 20, lines 33-39).

9. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,658,240 to Urdahl in view of US 5,135,667 to Schoendorfer et al.

In the specification and figures, Urdahl discloses the method substantially as claimed by applicant (see rejection above) with the exception of establishing a particular anticoagulant ratio.

Urdahl discloses a blood separation method that includes the step of adding anticoagulant to whole blood during the procedure (see column 5, lines0-67). Schoendorfer discloses a method for blood separation and collection that adjusts the anticoagulant ratio in order to generate a higher component yield (see column 4, lines 15-26). In particular, Schoendorfer discloses that an anticoagulant ratio of 6% greatly increases platelet yield (see column 13, lines 19-32). Schoendorfer thus demonstrates that AC ratio is a result-effective variable, wherein adjustment of the variable ratio affects the ultimate component yield. Therefore, it would have been obvious to one

having ordinary skill in the art to modify the method disclosed by Urdahl to adjust the AC ratio to the 6% disclosed by Schoendorfer, since it has been held that discovering an optimum value of a result-effective variable involves only routine skill in the art. See MPEP 2144.05.

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,658,240 to Urdahl in view of US 5,607,579 to Latham, Jr, et al.

In the specification and figures, Urdahl discloses the method substantially as claimed by applicant (see rejection above) with the exception of recirculating and returning an uncollected component to the patient.

Latham discloses a blood separation and collection method that uses uncollected, recirculated plasma to dilute whole blood entering the separation chamber to widen the buffy coat an enhance platelet collection efficiency and minimize WBC contamination (see column 2, lines 5-40). Once the desired platelets are collected, the uncollected components (including the recirculated plasma) are returned to the patient (see column 5, lines 47-60). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the step of recirculating and returning an uncollected component to the patient as disclosed by Latham to the blood separation and collection procedure as disclosed by Urdahl, in order to enhance component collection efficiency, as taught by Latham (see column 2, lines 5-40).

Allowable Subject Matter

11. Claims 14 and 19-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and correcting all the claim objections listed above.

12. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest the methods claimed by applicant.

With regard to claim 14, the prior art fails to suggest the method of claim 9 in combination with the step of changing the packing factor during various collection modes, along with the other steps and limitations of the claims.

With regard to claims 19 and 20, the prior art fails to suggest the method of claim 1 in combination with the step of adding anticoagulant and replacement fluid in the specific manner claimed by applicant, along with the other steps and limitations of the claims.

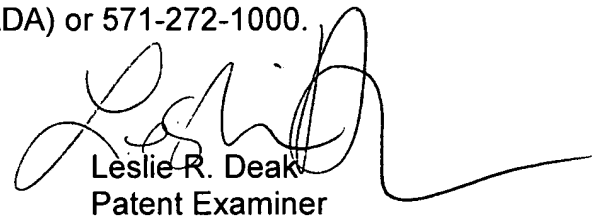
With regard to claims 21-23, the prior art fails to suggest the method of claim 1 in combination with the particular set-up step as claimed by applicant, along with the other steps and limitations of the claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Leslie R. Deak
Patent Examiner
Art Unit 3761
26 September 2006